



*Advancing Quality Healthcare  
Through Over-the-Counter Medicines  
and Nutritional Supplements*

## CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

March 25, 2004

Charles J. Ganley, M.D.  
Director, Division of OTC Drug Products,  
Office of Drug Evaluation V  
Center for Drug Evaluation & Research  
Food and Drug Administration  
5600 Fishers Lane (HFD-560)  
Rockville, MD 20857

Re: Docket No. 81N-0033

Dear Dr. Ganley:

Reference is made to your letter dated 29 October 2002 in which the Division of OTC Drug Products and the Division of Dermatologic and Dental Drug Products responded to our proposed research program on benzocaine for temporary relief of pain due to toothache (letter dated 21 June 2002).

In response to your feedback letter, the CHPA Benzocaine Task Group sponsored a pilot clinical study with a 20% benzocaine-containing oral care product. Results of this study addresses several of the key questions outlined in the 29 October 2002 feedback letter, including assessment of the subject's comprehension of the label directions for dosing, methodology to assess efficacy, and the duration of treatment effect. In addition, we have completed an updated safety assessment based on reports of methemoglobinemia associated with the use of oral benzocaine products for toothache.

We, therefore, request a meeting with the Agency to discuss the following:

- 1) results of the pilot study
- 2) the proposed protocol to evaluate 10% and 20% benzocaine
- 3) the proposed OTC label

We will provide a briefing document three weeks in advance of the scheduled meeting date that will provide the following information:

- 1) questions we would like the Agency to address
- 2) a list of attendees from industry and CHPA
- 3) the final report for the completed pilot study
- 4) the proposed protocol to evaluate 10% and 20% benzocaine
- 5) the proposed OTC label
- 6) other relevant background information

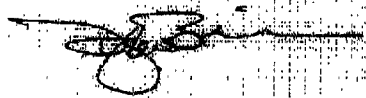
81N-0033

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- 2 -

We look forward to meeting with you in the near future. Please do not hesitate to contact me if you have any questions or need additional information.

Sincerely,



Douglas Ws. Bierer, Ph.D.  
Vice President – Regulatory & Scientific Affairs

DB/mm

cc: Elaine G. Abraham (HFD-560)